REMARKS

DOUBLE PATENTING

Claims 10-37 stand provisionally rejected under 35 U.S.C.§101 as claiming the same invention as that of claims 1-4,8, and 9 of the co-pending, commonly-owned U.S. Patent Application, Serial No. 09/311,487.

Applicants are amending this application to cancel claims 10-37 in this application.

Reconsideration and withdrawal of this ground of rejection are urged.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

Claims 1-9 stand provisionally rejected under the judicially-created obviousness-type double patenting doctrine as being unpatentable over claims 10-14, 18-24, 26, 27, 44-46, 50, 54, 58, and 59 of co-pending, commonly-owned U.S. Patent Application Serial No. 09/311,487.

A Terminal Disclaimer executed by the undersigned attorney of record in compliance with 37 C.F.R. 1.321(c) is enclosed, and this ground of rejection should be removed.

Claims 1-37 stand provisionally rejected under the judicially-created obviousness-type double patenting doctrine as being unpatentable over claims 1-5, 9-15,19-25, 29-35, 40-45, 49-55, 59-65, and 70 of co-pending, commonly-owned U.S. Patent Application Serial No. 09/650, 841.

A Terminal Disclaimer executed by the undersigned attorney of record in compliance with 37 C.F.R. 1.321(c) is enclosed, and this ground of rejection should be removed.

Claims 1-37 stand provisionally rejected under the judicially-created obviousness-type double patenting doctrine as being unpatentable over claims 1-43 of co-pending, commonly- owned U.S. Patent Application Serial No. 09/464, 425.

A Terminal Disclaimer executed by the undersigned attorney of record in compliance with 37 C.F.R. 1.321(c) is enclosed, and this ground of rejection should be removed.

Claims 1-37 stand provisionally rejected under the judicially-created obviousness-type double patenting doctrine as being unpatentable over claims 1-4 and 8-10 of commonly-owned U.S. Patent No. 6,172,046.

A Terminal Disclaimer executed by the undersigned attorney of record in compliance with 37 C.F.R. 1.321(c) is enclosed, and this ground of rejection should be removed.

CLAIM REJECTION – 35 U.S.C.§103(a)

Claims 1-37 stand rejected under 35 U.S.C.§(a) as being unpatentable over Chemello, et al(Journal of Hepatology,1994, Vol 21(Suppl. 1),pageS12, Abstract No.GS5/29)., Grint, et al.(EP 0 707 85A2), and Gilbert, et al.(WO 95/13090)

Applicants are amending this application by amending claims 1-9 to specify that the therapeutically effective induction dosing amount of pegylated interferon-alfa administered per week in the a first treatment time period is more than the therapeutically effective induction dosing amount of pegylated interferon-alfa administered per week in the second treatment time period, and the sum of the first and the second treatment time periods is about 40 to about 50 weeks.

Basis for this amendment is found, for example, in the claims as originally filed, as well as in the specification on page 3, line 15 to page 4, line 6, page 4, lines 29-31, and page 5, line 8 to page 7, line 27.

Entry of this amendment under theprovisions of 37 C.F.R.§ 1.116 are respectfully requested.

Chemello et al. discloses administering 15mg/kg of ribavirin and 3MIU of interferon alfa, TIW to a pilot group of HCV patients for six months. Nowhere does Chemello et al. disclose or suggest (1) replacing natural interferon alfa with pegylated interferon alfa, much less(2) administering higher doses increasing the natural interferon alfa dose in a first treatment time period, nor(3) teach that such induction dosing would be safe or effective in knocking down the HCV-RNA viral load; nor(4) extending the treatment period of time beyond six months

None of these deficiencies are cured by or Grint, et al.

Grint, et al. disclose a low dose of each of the drugs in combination therapy to reduce the side effects associated with administration of ribavirin and alfa interferon. See, Grint, et al. at page 3, line 19 to page 4, line 6 (or Grint, et al., col. 2, line 40 to column 5, line 11). Use of doses of 500 to no more than 800 mg of ribavirin and of doses of less than 3 million international units of interferon alfa- preferable 1 to no more than 2 million international units are taught. These doses are below the effective amounts of each drug taught and claimed by Applicants to be the "effective amount".

Moreover, Grint, et al. is directed to lower doses of each drug in the combination therapy to lower the side effects associated with the approved (higher) doses of interferon alfa and ribavirin. No motivation is thus provided to increase the amount of interferon, or increase the treatment time beyond six months as Applicants have discovered and claimed.

None of the deficiencies of Chemello, et al and/or Grint, et al. are cured by Gilbert, et al. which discloses alfa interferon conjugates are useful to treat many disease states. There is no direction in Gilbert, et al. to enable one skilled in the art to make the many modifications in dosing and dosing regimen, much less combine pegylated interferon alfa with a specific drug, ribavirin, to treat a specific disease, HCV.

Applicant assets that there is no direction or motivation provided in Chemello, et al., Grint, et al., or in Gilbert, et al., alone or in combination, to enable one skilled in the art to make the many modifications to bridge the gap to arrive at Applicants' claimed invention as amended without using Applicants' specification and claimed invention as a template.

Reconsideration and withdrawal of this ground of rejection are urged.

Applicants respectfully submit that none of the references, alone or in combination, make obvious the claimed invention, as amended.

If Applicants can be of any assistance in advancing prosecution, please call the undersigned attorney of record.

Respectfully submitted,
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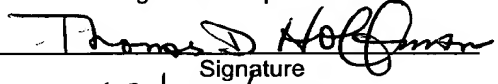
December 14, 2001

Thomas D. Hoffman
Registered Representative



Signature

12/14/2001
Date

APPENDIX I

Claim Version With Markings To Show Amendments

1(Amended). A method of treating patients having chronic hepatitis C infections which comprises (1) administering a therapeutically effective induction dosing amount of ribavirin and a therapeutically effective induction dosing amount of pegylated interferon-alfa for a first treatment time period sufficient to substantially lower detectable HCV-RNA, followed by (2) administering a therapeutically effective amount of ribavirin and an therapeutically effective amount of pegylated interferon-alfa for a second treatment time period sufficient to eradicate detectable HCV-RNA at least by the end of the second treatment time period and to maintain no detectable HCV-RNA for at least 24 weeks after the end of the second treatment time period, wherein the therapeutically effective induction dosing amount of pegylated interferon-alfa administered per week in the a first treatment time period is more than the therapeutically effective induction dosing amount of pegylated interferon-alfa administered per week in the second treatment time period, and the sum of the first and the second treatment time periods is about 40 to about 50 weeks.

Claims 10 to 37 are cancelled without prejudice.